Resolution II: USP–NF Monograph Modernization

USP will meet the needs of the US Food and Drug Administration (FDA), industry, and other stakeholders for modern Monographs within USP–NF. USP will work to eliminate the existing backlog of monographs in need of modernization and proactively evaluate and update monographs to maintain their relevance given scientific advances and evolving manufacturing and regulatory approaches. USP will work with industry and FDA to explore new strategies for sharing analytical methods and specifications needed to modernize monographs.

In FY 2019 USP continued to make significant progress toward accomplishing this Resolution.

USP developed and modernized more than 250 documentary standards and completed more than 150 monograph omissions from the USP–NF. These efforts ensure that USP is on track to meet FY 2020 Up-To-Date targets and to ensure that the compendia are as current as possible for industry and FDA.

In alignment with Up-To-Date efforts, USP engaged with the FDA to identify and prioritize the modernization of opioid monographs; this work supported the agency in its efforts to address the misuse and abuse of opioids.

We collaborated with the FDA, the Consumer Health Products Association and over-the-counter (OTC) drug manufacturers to continue to develop novel approaches to OTC standards. We focused on establishing flexible standards and pathways that allow OTC manufacturers to innovate and improve their non-prescription products while still meeting the FDA’s standard of quality.

To support the FDA’s Drug Competition Action Plan, we prioritized the development and modernization of quality standards included in the FDA’s list of off-patent drugs for which generic alternatives are not available.

Finally, USP continues its journey of transformation to a culture of continuous learning and improvement in which Up-To-Date is not just an initiative but a new way of working.

USP will continue to transform its standards-setting processes, systems and culture to improve quality and efficiency. We will continue to strengthen our strong partnerships with the FDA, industry and key stakeholders to support efforts that address the misuse and abuse of opioids, to promote the competition of generic medicines and to develop flexible approaches to establishing monographs for OTC medicines.

Key Accomplishments

- Developed and modernized more than 250 documentary standards
- Omitted more than 150 monographs from the USP–NF
- Engaged with the FDA to identify and prioritize the modernization of opioid monographs
- Continued to develop novel approaches to OTC standards
- Prioritized the development and modernization of quality standards to support the FDA’s Drug Competition Action Plan